# Virginia Department of Health <a href="Masal Swabbing Procedure and Performance of BinaxNOW">Nasal Swabbing Procedure and Performance of BinaxNOW</a> COVID-19 Ag Card

The following checklist identifies skills and procedures needed for nasal swab collection and testing using the BinaxNOWAntigen Card test for diagnosis of COVID-19. The appropriate supervisor should document competency and proficiency by each testing operator.

No.	Task Steps	Pass
1.	Participate in <b>TRAIN COURSE</b> # <b>1094708</b> . This course contains the Abbott	
	BinaxNOW COVID-19 Ag Card Training videos.	
2.	Assemble supplies: BinaxNOWTM COVID-19 Ag Card Kit (check expiration date on the	
	outside box): Abbott Patient Collection Nasal Swab, BinaxNOW™ COVID-19 Ag Card,	
	Extraction Reagent. Additional supplies: patient labels (if using), stopwatch/timer/clock,	
	PPE (see PPE guidance for antigen testing) and biohazard container, hand sanitizer, as	
	needed. If not testing immediately, gather Abbott Swab Transport Tube Accessory Pack.	
3.	Perform hand hygiene.	
4.	Quality control must be performed prior to testing: 1) When a new shipment of BinaxNOW antigen cards is received or 2) A new untrained operator performs the test (see separate guidance for QC procedure).	
5.	Open swab package and remove swab, taking care not to touch the tip on any surface or lay it down. (Use <i>only</i> Patient Collection Nasal Swabs provided in the BinaxNOW <sup>TM</sup> test kits).	
6.	Procedure for Nasal Swab collection:	
	May refer to Abbott BinaxNOW <sup>TM</sup> COVID-19 Nasal Swab Tech Tips: https://ensur.invmed.com/ensur/contentAction.aspx?key=ensur.541049.S2R4E4A3.20200905.10292.43572	
	a. Carefully insert the dry nasal swab into the <b>nostril exhibiting the most drainage</b> , or the nostril that is <b>most congested</b> , if drainage is not visible.	
	b. Using gentle rotation, push the swab until resistance is met at the level of the	
	turbinate (usually ½ to ¾ of an inch into the nostril). Rotate the swab five (5) times or	
	more against the nasal wall, and then slowly remove from the nostril.	
	c. Using the same swab, repeat sample collection in the other nostril.	
7.	Procedure for Testing:	
	May refer to BinaxNOW™ COVID-19 Ag Card Procedure:	
	https://ensur.invmed.com/ensur/contentAction.aspx?key=ensur.523752.S2R4E4A3.20200905.10292.43570	
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	If testing right away (recommended):	
	*Ensure that all test components are at room temperature (15°-30°C) before use.	

- \*Write in the patient's name prior to performing the test using the two lines on the right side of the card. If using patient labels, they should be placed at the bottom of the card below the test window.
- \*Remove the test card from its pouch just prior to use and <u>lay it flat</u>.
- \*Be sure there is a blue line present at the Control Line prior to running the test (discard the test card if there is no blue line).
- **Step 1**: Add the extraction reagent to the BinaxNOW<sup>TM</sup> COVID-19 Ag Card by holding the bottle **vertically** (NOT at an angle), hovering ½ inch above the TOP HOLE, slowly adding six (6) drops. DO NOT touch the card with the dropper tip while dispensing.
- **Step 2**: Insert patient swab into the **BOTTOM HOLE** and firmly push upwards so that the swab tip is **visible** in the **TOP HOLE**.
- **Step 3**: Rotate (twirl) swab shaft 3 times **CLOCKWISE** (to the right). Do not remove swab (*Note: false negative results can occur if the sample swab is not rotated (twirled) prior to closing the card*).
- **Step 4**: Peel off adhesive liner from the right edge of the test card. Close and securely seal the card.
- **Step 5**: Read results in the window **15 minutes** after closing the card (*Note: In order to ensure proper test performance, it is important to read the result promptly at 15 minutes, and not before. Results should not be read after 30 minutes).*

<u>If not running test immediately</u>: Requires Abbott Swab Transport Tube Accessory Pack (*sold separately*). Testing must be performed within one hour of specimen collection.

- Do not return nasal swab specimen to original paper packaging.
- To avoid contamination and preserve sample integrity, place the nasal swab in a clean, unused, tightly capped plastic tube (*use Abbott Swab Transport Tube Accessory Pack*) and label it with the patient information.
- The sample is stable in the plastic tube at room temperature (15°-30°C) for up to one (1) hour prior to testing. If greater than one (1) hour delay occurs, dispose of the sample and collect a new sample.
- Follow the steps 1-4 above for testing within 1 hour of collection.

## 8. **Results Interpretation**:

<u>Negative</u>: A negative specimen will give a single pink/purple colored control line in the top half of the window, indicating a negative result. This Control Line means that the detection part of the test was done correctly, but no COVID-19 antigen was detected.

<u>Positive:</u> A positive specimen will give two pink/purple colored lines. This means that COVID-19 antigen was detected. Specimens with low levels of antigen may give a faint Sample Line. **Any visible pink/purple line is positive**.

<u>Invalid</u>: If no lines are seen, if just the Sample Line is seen, or the Blue Control Line remains blue, the assay is invalid. Invalid tests should be repeated.

<u>Disposal</u>: All components of this kit should be discarded as **Biohazard waste**, according to Federal, State, and local regulatory requirements.

9. Remove your gloves and perform hand hygiene.

## 10. **Reporting**:

- Report result to patient and provide **Abbott Fact Sheet for Patients** (*link below in Resources*).
- Report result to ordering provider and provide **Abbott Fact Sheet for Health Provider** (*link below in Resources*).
- Record result in CLIA Lab Log (see link in training documents).
- By law, all positive and negative COVID-19 test results from diagnostic testing or screening must be reported electronically to VDH within 24 hours, regardless of the test type. The following is the link to <u>VDH's Reporting Portal for Point-of-Care</u> (<u>POC</u>) Test Results:
  - <u>https://apps.vdh.virginia.gov/pocreporting/login/login.aspx</u>. This site may be used to meet the rapid reporting requirement for POC tests and allows for aggregating negative results for high-volume sites.
- Sharing results with patients *may* also be done using Abbott's NAVICA application, for those patients with internet access. For more information about this, please see: <a href="https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html">https://www.globalpointofcare.abbott/en/support/product-installation-training/navica-brand/navica-binaxnow-ag-training.html</a>

**Resources:** Provide resources as necessary.

Abbott BinaxNOW<sup>TM</sup> COVID-19 Ag Card Patient Fact Sheets:

#### English:

https://ensur.invmed.com/ensur/contentAction.aspx?key=ensur.523761.S2R4E4A3.2020 0817.10292.4364349

### Spanish:

 $\underline{\text{https://ensur.invmed.com/ensur/contentAction.aspx?key=ensur.524484.S2R4E4A3.2020}}\\ \underline{1006.11031.4303849}$ 

### **Fact Sheet for Health Providers:**

## English:

https://ensur.invmed.com/ensur/contentAction.aspx?key=ensur.523766.S2R4E4A3.2020 0817.10292.4371609

### Spanish:

https://ensur.invmed.com/ensur/contentAction.aspx?key=ensur.524487.S2R4E4A3.2020 1104.11031.4304333

Evaluator Date